

**REMARKS**

Claims 1-10 and 12-19 are currently pending in the application. By this amendment, claims 1, 2-4, 6, 12 and 14 are amended. The foregoing separate sheets marked as "Listing of Claims" show all the claims in the application, with an indication of the current status of each.

**Response to Amendment**

The Examiner has objected to the amendment filed 10/11/05, due to the purported introduction of new matter by the amendment of claim 1 which replaced the recitation of "comprising" by the phrase "consisting essentially of". Claim 1 has hereby been amended to remove the phrase "consisting essentially of", thereby making moot this objection.

**Claim Rejections: 35 USC § 112, second paragraph**

Claims 1-10 and 12-19 stand rejected under 35 USC § 112, second paragraph, as indefinite. This rejection is traversed. The Examiner's holding of indefiniteness was based on the introduction of the phrase "consisting essentially of" into claim 1 by a previous amendment. Claim 1 has hereby been amended to remove the phrase "consisting essentially of", thereby making moot this rejection.

In view of the foregoing, Applicant requests reconsideration and withdrawal of this rejection.

**Claim Rejections: 35 USC § 102(b)**

The Examiner has maintained the previous rejection of claims 1-2, 6-7, 9-10 and 13 under 35 USC § 102(b) as anticipated by either Olsen et al. (hereafter “Olsen”) and/or Lunn et al., (hereafter “Lunn”). This rejection is traversed.

The present invention is based on surprising discoveries concerning the hemagglutinin (HA) protein molecule of equine influenza virus. The HA molecule is translated as a precursor polypeptide, HAO, which is post-translationally modified by proteolytic cleavage to produce two cleavage products, polypeptide chains HA1 and HA2. HA1 and HA2 remain associated, however, via non-covalent interactions. Use of full-length HA (i.e. HA including both HA1 and HA2) as a vaccine has been reported. However, Applicants have discovered that full-length HA is not required to elicit a protective immune response, and, in fact, use of the full-length protein is not optimal. Surprisingly, when the HA2 portion of HA is eliminated, and HA1 alone is utilized in a vaccine preparation, superior immune protection is observed. The use of HA1 alone as a vaccine is the basis of the present application.

In the previous response, claim 1 was amended to include the phrase “consisting essentially of”. The Examiner’s justification of claim rejections in the 01/05/2006 Office Action are based on the interpretation of this phrase. Claim 1 has hereby been amended to remove this phrase, thereby making moot the Examiner’s rejection.

Claim 1 has hereby been amended to recite that the form of HA that is utilized in the invention is HA1 from which HA2 is absent. More precisely, the DNA that is included in the

vaccine preparation comprises “sequences which encode an HA1 protein from which HA2 is absent”, i.e sequences encoding HA2 are excluded. Thus, Applicant submits that the element that is excluded from the vaccine (HA2) is sufficiently described in claim 1 as amended.

Support for this amendment is found in the specification, for example, in the following sentences of paragraph 66: “We report here that, [with] the expression of HA1 alone is sufficient to elicit protective immunity. Omission of the HA2 may circumvent a requirement for enzymatic processing, as a tissue specific protease is required to cleave the precursor HAO into HA1 and HA2. Furthermore, in the absence of HA2, synthesized HA1 will not be membrane bound, and hence allowing more HA1 molecules to be released and taken up by antigen presenting cells to elicit stronger immune response.”

The subject matter of the present invention obviously differs widely from that of Olsen and Lunn. Olsen and Lunn teach only the use of full-length HA, i.e. HA in which both HA1 and HA2 are present. A vaccine comprising HA1 alone, from which HA2 is excluded, is neither shown nor suggested by either reference. Thus, the subject matter of the present invention, as claimed unambiguously in amended claim 1, is patentable over these two references.

In view of the foregoing, Applicant requests reconsideration and withdrawal of this rejection.

**Claim Rejections: 35 USC § 103**

Examiner has maintained the previous rejection of claims 3-5, 8, 12 and 14-19 under 35 USC § 103 as anticipated by either Olsen et al. (hereafter “Olsen”) and/or Lunn et al., (hereafter “Lunn”) in combination with various secondary references. This rejection is traversed.

The Examiner’s argument is based on the inclusion of the phrase “consisting essentially of” in claim 1. Claim 1 has hereby been amended to exclude this phrase, thereby making moot this basis of the rejection.

As described above in the section dealing with the 35 USC § 102(b) rejection, claim 1 has hereby been amended to unambiguously recite the subject matter of the invention: a vaccine preparation containing DNA that encodes HA1 but not HA2. Thus, Applicant submits that the element that is excluded from the vaccine (HA2) is adequately and accurately described in claim 1, and thus in dependant claims 3-5, 8, 12 and 14-19. Neither Olsen nor Lunn show or suggest a vaccine preparation from which HA2 is absent, and thus the subject matter of the present invention cannot reasonably be deemed obvious in view of any combination of either of those references with any other reference(s).

In view of the foregoing, Applicant requests reconsideration and withdrawal of this rejection.

**Other matters**

Dependent claims 4, 6, 12 and 14 have hereby been amended to accord with the language of amended claim 1, i.e. to recite “sequences that encode an HA1 protein from which HA2 is absent” rather than “an HA1 encoding sequence”.

Claim 2 has hereby been amended to recite that it is a strain of equine-2 influenza virus, not a DNA sequence, that is being selected from the Markush group recited in the claim; claim 3 has been amended to accord with amended claim 2.

Applicant submits that these additional amendments do not add any new matter, being entirely formal in nature, and respectfully requests entry of the amendments, and allowance of the claims.

**Conclusion**

In view of the foregoing, it is requested that the application be reconsidered, that claims 1-10 and 12-19 be allowed, and that the application be passed to issue.

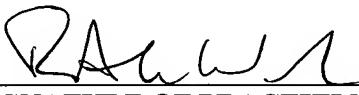
Should the Examiner find the application to be other than in condition for allowance, the Examiner is requested to contact the undersigned at 918-599-0621 (fax: 918-583-9659; email: [aweeks@fellerssnider.com](mailto:aweeks@fellerssnider.com)) to discuss any other changes deemed necessary in a telephonic or personal interview.

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If an extension of time is required for this response to be considered as being timely filed, a conditional petition is hereby made for such extension of time. Please charge any deficiencies in fees and credit any overpayment of fees to Attorney's Deposit Account No. 06-0540.

Respectfully submitted,

4/3/06  
DATE

  
SIGNATURE OF PRACTITIONER

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